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Helsinki, 19 May 2017

Addressee: [redacted]

Decision number: CCH-D-2114360325-54-01/F
Substance name: Octene, hydroformylation products, low-boiling
EC number: 273-110-1
CAS number: 68938-03-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 2 December 2013
Registered tonnage band: over 1000 tonnes/year

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Composition of the substance (Annex VI, Section 2.3.)**

2. **Description of the analytical methods (Annex VI, Section 2.3.7) for the registered substance**

   - **Identification and quantification of the constituents**

3. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2; test method: EU B.26/OECD TG 408) in rats with the registered substance;**

4. **Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance specified as follows:**
   - **Ten weeks premating exposure duration for the parental (P0) generation;**
   - **Dose level setting shall aim to induce some toxicity at the highest dose level;**
   - **Cohort 1A (Reproductive toxicity);**
   - **Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation;**

5. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25/OECD TG 309) at a temperature of 12 °C with the registered substance as specified in Appendix 1, Section 5;**

6. **Identification of degradation products (Annex IX, Section 9.2.3.) using an appropriate test method with the registered substance as specified in Appendix 1, Section 6;**

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7. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, [aqueous exposure/dietary exposure]) with the registered substance as specified in Appendix 1, Section 7;**

8. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5; test method: Daphnia magna reproduction test, EU C.20/OECD TG 211) with the registered substance;**

You are required to submit the requested information in an updated registration dossier by **26 May 2020** except for the information requested under point 3 for a sub-chronic toxicity study (90-day) which shall be submitted in an updated registration dossier by **28 May 2018**. You may only commence the extended one-generation reproductive toxicity study as requested under point 4 after **28 August 2018**, unless an indication to the contrary is communicated to you by ECHA before that date. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/web/guest/regulations/appeals.]

Authorised[2] by Claudio Carlon, Head of Unit, Evaluation E2

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix 1: Reasons

Identification of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Composition of the substance (Annex VI, Section 2.3.)

Annex VI, section 2.3 of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, according to chapter 4.3 of the Guidance on substance identification, for UVCB substances such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature; and
- For each constituent and group of constituents, the typical, minimum and maximum concentration levels shall be specified.

ECHA notes that the reported composition is referring to "[redacted]" and "[redacted]" without any further subdivision. On the other hand, the substance is identified in section 1.1 as "[redacted]" with the following description "[redacted]".

Each (group of) constituents of your substance needs to be reported separately as prescribed by the Guidance. At least four relevant groups of constituents are mentioned in the identification of the registered substance: [redacted].

To confirm the identity of the substance described in section 1.1 of the IUCLID dossier, the composition of the substance needs to be specified at least at the level of detail refered to in the identification.

Hence, you shall submit a refined report of the composition of the registered substance, which is listing at least the aforementioned groups of constituents with their carbon chain length distribution, a generic description of their chemical nature (expected or known constituents), and their concentration values as specified above.

You shall ensure that there is sufficient analytical information included in section 1.4 of the IUCLID dossier to identify and quantify the substance and to verify the information in IUCLID section 1.2.

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Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website.

2. Description of the analytical methods (Annex VI, Section 2.3.7.)

The description of analytical methods or appropriate bibliographical reference for the identification of the substance is a formal information requirement of Annex VI, Section 2.3.7

ECHA notes that the dossier contains analytical data, more specifically a gas chromatogram, nuclear magnetic resonance spectra, an infra red and a ultraviolet spectrum. None of these methods was described in such a way that enables identification and quantitation of the consituents of the registered substance. Therefore ECHA concludes that the dossier does not contain the description of any analytical method suitable to identify and quantify the (groups of) constituents required to be reported in the composition of the registered substance.

As the analytical methods and their results are a pre-requisite for reporting the composition, ECHA considers that analytical data needs to be submitted to support each reported (group of) constituents in the composition in section 1.2 of the technical dossier.

Therefore, in line with Annex VI, Section 2.3.7, the Registrant is requested to submit a suitable description of the analytical methods used for the identification and quantification of the constituents/groups of constituents required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

Regarding how to report the requested information in IUCLID, the information should be attached in IUCLID section 1.4.

3. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" [redacted], 2010) (test method: OECD TG 422). You also provided the following justification for the adaptation: "*A 90-day repeated dose oral toxicity study has not been conducted on Oxooil LS9. However, since relevant, specific target organ toxicity was not observed at 300 mg/kg/day in an OECD 422 screening study, it is unlikely that Oxooil LS9 will represent a long-term toxic risk.*"

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ECHA notes that this study does not provide the information required by Annex IX, Section 8.6.2., since this study provides information on the toxicological effects arising from repeated exposure over a period of five weeks only, hence over a shorter exposure duration than the the 13 weeks of the sub-chronic toxicity study (90-day). In addition, the statistical power of the OECD TG 422 screening study is less than that of a 90-day study further reducing the sensitivity of the screening study as compared to the 90-day study. The No-Observed-Adverse-Effect-Level (NOAEL) for systemic toxicity in adult male and female rats treated with the test substance for up to 5 weeks is 100 mg/kg/day, however, it cannot be concluded whether the test substance willl represent a long-term risk solely depending on the findings of this screening study.

You have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a "combined sub-chronic vapour inhalation study with reproduction/developmental toxicity screening test" ([redacted], 2007), performed by the inhalation route (OECD TGs 422 and 413) with the analogue substance Isooctene (EC No 203-486-4). However, ECHA notes that the adaptation provided does not meet the specific rules for adaptation of Annex XI, Section 1.5., because you failed to provide "*adequate and reliable documentation*" explaining and justifying the read across hypothesis with adequate data.

In the technical dossier you only provided the following justification for using the 90-day study of the source substance as a read-across to the target substance: *"A repeated dose inhalation study is not available for Oxooil LS9. However, a substance, Isooctene (CAS 11071-47-9), which is analogous to the potentially more toxic components of Oxooil LS9 ([redacted]), has been tested in a 90-day inhalation study in rats (combined OECD 422 and 413)...The substance is considered to be a low toxic risk by both the dermal and inhalation routes of exposure."*

According to the provisions of Annex XI, section 1.5 of the REACH Regulation, the properties of substances used in read-across approaches must be likely to be similar or follow a regular pattern. ECHA observes that no information supporting your read-across hypothesis and claim of similarity in the structure, physicochemical and toxicological properties, of the source and the target substances is included in the registration dossier. Moreover, the source substance is only one of the toxic components of the target substance, hence, there can be other potentially toxic components that you have not taken into consideration.

In the absence of information supporting the hypothesis according to which the source substance is toxicologically similar to one of the toxic components of the target substance, ECHA concludes that you have not provided an adequate basis for predicting the properties of the registered substance from the source substance, as required by the provisions of Annex XI, section 1.5 of the REACH Regulation.

Therefore, your adaptation of the information requirement is rejected.

Furthermore, the most appropriate route for the sub-chronic toxicity study with the registered substance, is the oral and not the inhalation route, as provided with the source substance. As explained below, the oral route should be further examined since absorption of this substance via the gastro-intestinal tract was clearly demonstrated following subacute administration in the rat.

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Evidence of general distribution to the tissues and organs was revealed in this study by the macroscopically abnormal pink discolouration in various organs, probably due to the presence of one of the toxic constituents of the test substance. Additionally, according to the chemical safety report (CSR), it has been reported that "*Although absorption would be expected via the lung, repeated dose toxicity information would indicate that it is unlikely to be any greater than by oral exposure.*"

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. The test substance is a liquid with a (high) vapour pressure of 4.8kPa and a very high boiling point (120°C). The substance does not have any spray applications as it is used as a fuel by both professional workers and consumers.

From the information reported in the dossier and the chemical safety report, the acute systemic effects and local effects indicate a low acute toxicity value (LD50 > 2000 mg/kg bw.), for oral and dermal routes. A degree of absorption would be expected via the lungs, however, as reported in the CSR, the toxicological evidence indicates that it is unlikely to be any greater than by the oral route. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

4. Extended one-generation reproductive toxicity study

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(e) and 13(4) of the REACH Regulation, a technical dossier registered at more than 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.
The basic test design of an extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443 with Cohorts 1A and 1B, without extension of Cohort 1B to include a F2 generation, and without Cohorts 2A, 2B and 3) is a standard information requirement as laid down in column 1 of 8.7.3., Annex X. If the conditions described in column 2 of Annex X are met, the study design needs to be expanded to include the extension of Cohort 1B, Cohorts 2A/2B, and/or Cohort 3. Further detailed guidance on study design and triggers is provided in in ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015).

Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

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a) The information provided

In the technical dossier you have provided a study record for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" ([redacted], 2010)(test method: OECD TG 422). However, this study does not provide the information required by Annex X, Section 8.7.3. because it does not cover key elements, such as exposure duration, life stages and statistical power of an extended one-generation reproductive toxicity study. More specifically, the main missing key elements are: 10 weeks pre-mating exposure duration, at least 20 pregnant females per group, and an extensive postnatal evaluation of the F1 generation. In addition, considering that the criteria for extension of the Cohort 1B are met for the registered substance according to column 2 of Annex X, Section 8.7.3., also the information for those properties is missing.

You also provided that "*[a] 2-generation reproductive toxicity study has not been conducted on Oxooil LS9. However, in the complete absence of any reproductive effect at the limit dosage of 1000 mg/kg/day in an OECD 422 screening study, it is considered unlikely that Oxooil LS9 will represent a reprotoxic risk.*" However, ECHA notes that since the registered substance is registered at a tonnage band of 1000 tonnes or more per year, the extended one generation reproductive toxicty study is an information requirement according to Annex X, Section 8.7.3. Therefore, your adaptation of the information requirement is rejected.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint. Thus, an extended one-generation reproductive toxicity study according Annex X, Section 8.7.3. is required. The following refers to the specifications of this required study.

b) The specifications for the study design

Information from studies to be conducted before the extended one-generation reproductive toxicity study

The sub-chronic toxicity study shall be conducted before the extended one-generation reproductive toxicity study and the results from that study shall be used, among other relevant information, to decide on the study design of the extended one-generation reproductive toxicity study following ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015). The sub-chronic toxicity study may provide information on effects that is relevant for triggers (e.g. weight changes and histopathological observations of organs as indication(s) of one or more modes of action related to endocrine disruption which may meet the toxicity-trigger for extension of Cohort 1B or as evidence of specific mechanism/modes of action and/or neurotoxicity and/or immunotoxicity which may meet the particular concern criteria for developmental neurotoxicity and/or developmental immunotoxicity cohorts).

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Premating exposure duration and dose-level setting

To ensure that the study design adequately addresses the fertility endpoint, the duration of the premating exposure period and the selection of the highest dose level are key aspects to be considered. According to ECHA Guidance, the starting point for deciding on the length of premating exposure period should be ten weeks to cover the full spermatogenesis and folliculogenesis before the mating, allowing meaningful assessment of the effects on fertility.

Ten weeks premating exposure duration is required if there is no substance specific information in the dossier supporting shorter premating exposure duration as advised in the ECHA *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015). In this specific case ten weeks exposure duration is supported by the lipophilicity of the substance (log K_{ow} 5.4-6.2 at 26°C and pH 7.35) to ensure that the steady state in parental animals has been reached before mating.

The highest dose level shall aim to induce some toxicity to allow comparison of effect levels and effects of reproductive toxicity with those of systemic toxicity. The dose level selection should be based upon the fertility effects with the other cohorts being tested at the same dose levels.

If there is no existing relevant data to be used for dose level setting, it is recommended that results from a conducted range-finding study (or range finding studies) are reported with the main study. This will support the justifications of the dose level selections and interpretation of the results.

Extension of Cohort 1B

If the column 2 conditions of 8.7.3., Annex X are met, Cohort 1B must be extended, which means that the F2 generation is produced by mating the Cohort 1B animals. This extension provides information also on the sexual function and fertility of the F1 animals.

The use of the registered substance is leading to significant exposure of consumers and professionals because the registered substance is used by professionals and consumers as fuels.

Furthermore, there are indications that the internal dose for the registered substance will reach a steady state in the test animals only after an extended exposure because the partition coefficient log K_{ow} for the registered substance is 5.4-6.2 (at 26°C and pH 7.35).

According to ECHA Guidance on information requirements and chemical safety assessment (version 4.1, October 2015) Chapter R.7a, Appendix R.7.6–2, "*an octanol-water partition coefficient (logK_{ow}) value (e.g. above 4.5) indicates (bio)accumulative potential*". In the endpoint summary of section 7.1 of the IUCLID registration dossier, you confirm the "*high n-octanol/water partition coefficient (Log Kow 5.4 to 6.2)*".

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Finally, there are indications for endocrine-disrupting modes of action because according to the "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" ([redacted] 2010) the following finding was observed: "*Seminal vesicles absolute and adjusted weights were slightly low in males that received 300 mg/kg/day when compared with Controls, with adjusted weights attaining statistical significance*". The finding is supported by the indication that the substance reaches the seminal vesicle: "*Males that received 300 mg/kg/day were observed to have abnormal pink colouration of the seminal vesicles*". According to ECHA's *Guidance on information requirements and chemical safety assessment* R.7a, chapter R.7.6 (version 4.1, October 2015) (p. 412), "*changes in reproductive organs and other endocrine organs (e.g. ... seminal vesicles ...)*" are an indication of an endocrine disruptor mode of action fulfilling the toxicity-trigger to extend the Cohort 1B.

Therefore, ECHA concludes that Cohort 1B must be extended to include mating of the animals and production of the F2 generation because the uses of the registered substance is leading to significant exposure of professionals and consumers and there are indications that the internal dose for the registered substance will reach a steady state in the test animals only after an extended exposure and there are indications of modes of action related to endocrine disruption from the available screening study (Huntingdon, 2010) for the registered substance.

The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/triggers must be documented.

Species and route selection

According to the test method EU B.56./ OECD TG 443, the rat is the preferred species. On the basis of this default assumption, ECHA considers that testing should be performed in rats.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

c) Outcome

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Extended one-generation reproductive toxicity study (test method EU B.56./OECD TG 443), in rats, oral route, according to the following study-design specifications:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce some toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation;

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Currently, the inclusion of Cohorts 2A and 2B (developmental neurotoxicity) and Cohort 3 (developmental immunotoxicity) are not requested. However, the sub-chronic toxicity study (90-day) requested in this decision (request *3*) and/or any other relevant information may trigger changes in the study design. Therefore, the sub-chronic toxicity study (90-day) is to be conducted first and the study results submitted to ECHA in a dossier update by **28 May 2018**. If, on the basis of this update and/or other relevant information, a need for changes to the study design is identified, ECHA will inform you by **28 August 2018** (i.e. within three months after expiry of the 12-month deadline to provide the sub-chronic toxicity study (90-day)) of its intention to initiate a new decision making procedure under Articles 41, 50 and 51 of the REACH Regulation to address the design of the extended one-generation reproductive toxicity study. If you do not receive a communication from ECHA by **28 August 2018**, the request of the present decision for the extended one-generation reproductive toxicity study remains effective and you may commence the conduct of the study and the results will need to be submitted by the deadline given in this decision **26 May 2020**.

Notes for your consideration

When submitting the study results of the sub-chronic toxicity study (90-day) you are invited to also include in the registration update your considerations whether changes in the study design are needed (see also *ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6 (version 4.1, October 2015)*).

Furthermore, after having commenced the extended one-generation reproduction toxicity study in accordance with the ECHA decision, you may also expand this study to address a concern identified during the conduct of it and also due to other scientific reasons in order to avoid a conduct of a new study. The justification for the changes in the study design must be documented. The study design must be justified in the dossier and, thus, the existence/non-existence of the conditions/ triggers must be documented.

5. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. of the REACH Regulation. Column 2 of Section 9.2.1.2 of Annex IX indicates that the study does not need to be conducted if the substance is highly insoluble in water or if the substance is readily biodegradable. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement providing the following justification for the adaptation *"In the absence of any biological degradation in the screening test, Oxooil LS9 is considered to be non biodegradable."*

However, ECHA notes that your adaptation does neither meet the specific rules for adaptation of Annex IX, Section 9.2.1.2., column 2 nor any general rule for adaptation of Annex XI because the substance is not readily biodegradable and the provided screening level information in the dossier leads to potentially P or vP conclusion and there is no information on the degradation products and their fate. In addition, the substance is moderately soluble (283 mg/L at 20° C).
According to the registration dossier, substance is volatile (vapor pressure of 48 hPa at 20°C). However, the substance is UVCB, and the report on substance composition needs

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improvement. As some of the constituents may not be volatile, simulation test in water cannot be waived off, and identification of degradation products is necessary.

In the technical dossier you have concluded that the substance is not readily biodegradable and that "*Based on the results from chapter 4.1.2 Biodegradation, Oxooil LS9 is persistent (P) and very persistent (vP) in the aquatic environment*".

Since the ready biodegrability test is supposed to be used in PBT assessment for screening purposes, ECHA considers that further information on degradation is needed for the PBT/vPvB assessment and for the identification of the degradation products. According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Impurities present in concentrations at or above 0.1 % are deemed to be relevant constituents of the substance. Indeed, Section R.11.4.1 (page 33) of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014) indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*". Prior to further bioaccumulation assessment it is therefore necessary to provide further information on each relevant constituent, impurity and additive relevant when they are present in concentration of ≥ 0.1% (w/w). Individual concentrations < 0.1 % (w/w) normally need not be considered.

In response to a Member State Competent Authority (MSCAs) proposals for amendment (PfA) ECHA clarifies the following. ECHA considers that at this stage the information in the CSA is not complete due to the data gaps addressed in this decision. On this basis, the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products.

In your response to a MSCAs PfA you indicated you will first further clarify the substance idenitity of the registered substance and secondly consider further options to assess this endpoint taking into account the properties of the registered substance and update your dossier accordingly.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

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One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*".

The Guidance on information requirements and chemical safety assessment R.7b (version 3.0, February 2016) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

You should provide information on the degradation of all relevant constituents, impurities and additives present in concentration of ≥ 0.1% (w/w) is fresh water. Alternatively, you should provide a justification for why you consider certain constituents, impurities or additives present in concentration of ≥ 0.1% (w/w) or certain constituent fractions/blocks as not relevant for the PBT/vPvB assessment.

In response to a Member State Competent Authority (MSCAs) proposals for amendment (PfA) ECHA clarifies the following. In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the "pelagic test" option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing Natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you are requested to explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

ECHA Secretariat acknowledges the comments you submitted and your intention to clarify the substance's composition before conducting any further degradation tests.

In your comments you reflected the challenges in testing the degradation of the registered UVCB substance with the components of varying volatily in OECD TG 309. Furthermore you proposed to repeat the OECD TG 310, with a smaller headspace to minimise the volatilisation of the substance. ECHA notes that you are free to conduct such a screening test without a testing proposal. However, request for conducting the OECD TG 309 is needed as described above in the draft decision to provide information on the half-life of the substance as well as information on potential degradation products.

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In your comments you further indicate that the substance identity needs clarification before further options to assess the biodegradability is considered. In addition, you indicate that the feasibility for read-across to a similar substance should be assessed before considering the performance of a complex test. You also highlight that a key element for the potential of biodegradation will be the level of branching of the constituents.

ECHA agrees on your approach to clarify the substance identity before conducting any further degradations test. ECHA acknowledges that you may adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. ECHA notes that any such adaptation should be scientifically justified, adequate and reliably documented. The justification should cover of all relevant constituents, impurities and additives present in concentration of ≥ 0.1% (w/w) is fresh water. Alternatively, a justification should be provided for why certain constituents, impurities or additives present in concentration of ≥ 0.1% (w/w) or certain constituent fractions/blocks were considered as not relevant for the PBT/vPvB assessment.

ECHA notes that if it is not feasible due to complexity of the substance to identify or isolate single constituents, the simulation test with UVCB substance may be conducted with fractions/blocks, in which the constituents are structurally similar or in which the constituents are to such extent similar that their degradation can be predicted to follow a regular predictable pattern. However, as described above, the selection of the fractions needs to be justified and justification should also cover why certain constituents were not considered relevant for the PBT/vPvB assessment.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision, as specified above: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309).
Notes for your consideration

Before conducting the requested test[s] you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4 and R.7.9.6 (version 3.0, February 2016) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) on PBT assessment.

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the test detailed above is available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

6. Identification of degradation products (Annex IX, Section 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the information does not need to be provided if the substance is readily biodegradable.

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ECHA notes that the registered substance is not readily biodegradable; your registration dossier does not contain information on the degradation products or an acceptable adaptation for this standard information requirement pursuant to the specific adaptation rules of Column 2 of Annex IX, Section 9.2.3, Column 2 or the general adaptation rules of Annex XI.

According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Section R.11.4.1 of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014) indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*". Therefore degradation products should be identified for each constituent and relevant impurity present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

In response to a Member State Competent Authority (MSCAs) proposals for amendment (PfA) ECHA clarifies the following. ECHA notes further that as explained fully in section (5) above, ECHA considers that with the current information gaps the CSA cannot be used to justify that there is no need to investigate further the degradation of the substance and its degradation products. ECHA notes further that the information requested here is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment

In your response to a MSCAs PfA you indicated you will first further clarify the substance idenitity of the registered substance and secondly consider further options to assess this endpoint taking into account the properties of the registered substance and update your dossier accordingly.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test method, the methods will have to be substance specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You may obtain this information from the simulation study also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

You should provide information on the degradation products of all relevant constituents, impurities and additives present in concentration of ≥ 0.1% (w/w). Alternatively, you should provide a justification for why you consider certain constituents, impurities or additives present in concentration of ≥ 0.1% (w/w) or certain constituent fractions/blocks as not relevant for the PBT/vPvB assessment.

ECHA Secretariat acknowledges your comments and your intention to clarify the substance's composition before conducting any specific tests, including the identification of degradation products.

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In your comments you state that the higher test substance concentrations than applied in the simulation test might be useful for the detection of degradation products and that the identification of all constituents or degradation products relevant for the PBT assessment might technically not be feasible. ECHA notes that OECD TG 309 describes that higher concentrations of the test substance (e.g., >100 µg/l) may be used in identification and quantification of major transformation products (pathway part). If there are analytical difficulties in identifying the degradation products in context of the OECD TG 309, higher test temperature than 12 °C is recommended for the degradation pathway part of the test.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision, as specified above:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, [aqueous exposure/dietary exposure]).

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.3. and by providing QSAR predictions for a number of substances.

You provided BCF (L/Kg) model predictions for eight different substances: n-Octane – 1220; 1-Octene – 481; 2-Methylheptane – 273; 7-Methylheptene-1 – 222; 2,4-Dimethylhexane – 244; 2,4-Dimethylhexene-1 – 242; Isononanol – 62; and Isononanal - 60. You state that the highest calculated BCF-value is for n-Octane: 1220 L/kg and that branched or unsaturated C8-hydrocarbons have lower BCF-values while oxygenated molecules such as Isononanol or Isononanal have much lower BCF-values. Therefore you assume that the BCF of n-octane is a reliable worst-case-scenario.

However, as laid out in Appendix 1, section 1 above, there is a lack of information on the constituents of the registered substance and consequently ECHA cannot assess the relevance of these predictions in the context of the bioaccumulation information requirement. Furthermore, the logKow of the registered substance is reported to be 5.2-6.2, while the logKow of n-Octane is ~4 which would suggest that there are constituents present in the substance with higher bioaccumulation potential than n-octane.

Consequently, ECHA concludes that your adaptation does not meet the general rule for adaptation of Annex XI; Section 1.3.

Therefore, your adaptation of the information requirement cannot be accepted.

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As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 2.0, November 2014) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2.

As specified in Section R.11.3.2.1 of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014), you must show in the PBT/vPvB assessment that you have taken into account the relevant constituents, impurities and additives. This is generally possible only if you include in the PBT/vPvB assessment appropriate justifications for all constituents, impurities and additives or for all fractions/blocks of the substance composition on why these are considered to be relevant or judged to be not relevant for the PBT/vPvB assessment, regardless of whether the substance identity of these could be ultimately determined or not. You may derive such reasoning quantitatively or qualitatively, by using the PBT/vPvB assessment principles as described in Section R.11.4. This also applies to all transformation/degradation products.

In response to a Member State Competent Authority (MSCAs) proposals for amendment (PfA) ECHA clarifies the following. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. If you decided to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision. You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

In your response to a MSCAs PfA you indicated you will first further clarify the substance idenitity of the registered substance and secondly consider further options to assess this endpoint taking into account the properties of the registered substance and update your dossier accordingly.

In your comments to the draft decision, you indicated your intention to first clarify the composition of the substance as requested under section 1 of this decision. You also agreed with the integrated testing strategies outlined in the notes for your consideration below.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision, as specified above: Bioaccumulation in fish: aqueous or dietary bioaccumulation fish test (test method: OECD TG 305)

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Notes for your consideration:

Before conducting testing, you are advised to consult the ECHA Guidance on the information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11. PBT/vPvB assessment, in particular to first conclude on whether the registered substance is not persistent (P) and not very persistent (vP) or whether it may fulfil Annex XIII of the REACH Regulation criteria of being P or vP and to consult the PBT assessment for Weight-of-Evidence determination and the integrated testing strategy for bioaccumulation assessment, in particular concerning relevant constituents, impurities, additives and degradation/transformation products. Also, you need to carefully consider the potential formation of stable degradation products with PBT/vPvB properties.

In addition, you are advised to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapters R.4, 5, 6, R.7b and R.7c. If you decide to adapt the testing requested according to the specific rules outlined in Annexes VI to X and/or according to general rules contained in Annex XI of the REACH Regulation, you are referred to the advice provided in practical Guides 4, 5 and 6.

8. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a long-term toxicity on aquatic invertebrates in the dossier that would meet the information requirement of Annex IX, Section 9.1.5.

ECHA notes that under 'Data waiving' you have selected "*other justification*", with a note that "*Since Oxooil LS9 is acutely harmful to daphnids, but not to fish or fresh water algae, a Daphnia magna reproduction test is proposed (OECD 211)*". However, since you have not indicated any testing proposal within IUCLID in the endpoint study record by selecting 'experimental study planned' in the field 'study result type', ECHA can only conclude that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5. and that the waiver cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your comments to the draft decision, you agreed to conduct testing for this endpoint, taking into account the impact of the volatility of the substance on the test design.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 3.0, February 2016) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

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Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

Notes for your consideration

Regarding the use of the Water Accommodated Fraction (WAF) approach, which the Registrant used when conducting the short-term toxicity stuy in invertebrates and fish, please note that the WAF approach is problematic when used with a test substance containing several constituents, such as a UVCB, as in the case of the registered substance.

In such cases the toxicity cannot be allocated to specific constituents directly and interpretation of the results in the risk assessment requires careful consideration taking into account differences in fate of the constituents in the environment. When constituents of varying solubility are present there can be partitioning effects which limit dissolution in the water. These effects should be minimised and appropriate loadings selected accordingly to allow an appropriate determination of the toxicity of the different constituents.

In that respect, it is critical that a robust chemical analysis is carried out to identify those constituents present in the water to which the test organisms are exposed. Additionally, chemical analysis to demonstrate attainment of equilibrium in WAF preparation and stability during the conduct of the test is required. Methods capable of identifying gross changes in the composition of WAFs with time are required such as ultra-violet spectroscopy or total peak area have been used successfully for this purpose.

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 36 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 48 months. Following ECHA's request to submit documentary evidence, you only provided the scheduling timelines for the studies to confirm the identity and composition of the registered substance, which should be completed by end of February 2017. Furthermore, you informed ECHA that after consulting the contract research service providers, "*the predetermined period for the implementation of the 90-day-study and the EOGRTS was estimated to be feasible*". However, "*an extension of the time period safely provides the timely submission of the dossier.*" Hence you are requesting ECHA to provide you with an additional 3 months "*for in-depth discussions between the two toxicological studies and internal handling of the study data*". ECHA notes that you failed to provide documentary evidence on why you require an additional 3 months. Therefore, ECHA has not modified the deadline of the decision.

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Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 17 May 2016.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the requests and the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposals for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-53 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2019.

2. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

3. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

4. In relation to the information required by the present decision, the sample of substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance composition manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of substance tested in the new test(s) is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.